

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/15/2009 has been entered.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, a thermally insulative layer and a layer of thermally poorly conductive material must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.

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- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 14, 16-18, 22, 27, 28, 31, 38-48** are rejected under 35 U.S.C. 102(b) as being anticipated by Webster (US 6,171,275).

5. **Regarding claims 14, 18 and 27**, Webster discloses a catheter comprising: an elongate body having a longitudinal axis (10); a unitary electrode(30; unitary is defined in the broadest interpretation from Merriam Webster as "of or relating to a unit" the electrode of Webster is one unit when connected together and secured in the interior of the cup electrode) having at least one bore(40) formed through the electrode, wherein the unitary electrode couples to and is disposed at a distal end portion of the elongate body; a conductive wire(16) extending through said elongate body and electrically coupled to said unitary electrode; and an irrigation channel(14) extending through said elongate body and fluidly coupled to a proximal portion of the at least one bore, wherein

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said at least one bore includes at least one fluid outlet branch(41) coupling to a lateral side of the unitary electrode and said at least one fluid outlet branch includes one of a thermally insulating interior casing and a layer of a thermally poorly conductive material disposed within said at least one fluid outlet branch (infusion tube 14 is made of polyamide which acts as a thermally insulating layer, this tubing extends into the central channel (40) and extends into separate branches 41 which would then insulate at least a portion of an outlet opening, there is no description of specific layers, therefore in the broadest interpretation any material that is thermally insulative and poorly conductive can be used as a material disposed within at least on outlet opening) and wherein the at least one fluid outlet branch is formed at an acute angle relative to the longitudinal axis (view figure 5; column 4, lines 28- column 5, line 5 and column 6, lines 27-43).

6. **Regarding claim 16**, Webster discloses a catheter according to claim 14, wherein said irrigation channel has a longitudinal axis and said at least one branch comprises a series of outlet openings that guide a fluid supplied through said irrigation channel and said at least one bore (view figure 5).

7. **Regarding claim 17**, Webster discloses a catheter according to claim 16, wherein the series of outlet openings are configured at an angle relative to the longitudinal axis, and wherein said angle comprises an angle of between about 30 degrees and about 90 degrees (column 4, line 67).

8. **Regarding claim 22**, Webster discloses the catheter according to claim 14, wherein said at least one bore terminates at an interface between said elongate body and said unitary electrode (view figure 5).

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9. **Regarding claim 28**, Webster discloses a catheter according to claim 27, wherein said irrigation channel has a longitudinal axis and the at least one outlet opening is adapted to deliver said fluid to an outer surface of said elongated body in an outflow direction, and wherein said outflow direction comprises an angle relative to said longitudinal axis (view figure 5).

10. **Regarding claims 31, 41, 42, 45, 46 and 48** Webster discloses a catheter, further comprising a temperature sensor coupled to the electrode at a distance from an interface formed between said elongate body and said unitary electrode (view figure 5 and column 7; lines 5-14).

11. **Regarding claim 38**, Webster discloses deploying a unitary electrode(30) body, having a longitudinal axis, coupled to a distal portion of an elongate flexible shaft into contact with a volume of a target tissue, wherein said unitary electrode body includes a longitudinal fluid passageway(14) formed from a proximal end portion through to a less proximal surface portion and the fluid passageway couples to at least one outlet opening(41) formed at an acute angle relative to the longitudinal fluid passageway (view figure 5); measuring a temperature of said unitary electrode body with a temperature sensor coupled to the electrode body and spaced from the fluid passageway (column 7; lines 5-14) and dispensing fluid from a remote vessel through an irrigation channel within the elongate body fluidly coupled to said fluid passageway, wherein at least a portion of an interior surface of said at least one outlet opening comprises a layer of a thermally insulative material (infusion tube 14 is made of polyamide which acts as a thermally insulating layer, this tubing extends into the central channel (40) and extends

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into separate branches 41 which would then insulate at least a portion of an outlet opening, there is no description of specific layers, therefore in the broadest interpretation any material that is thermally insulative and poorly conductive can be used as a material disposed within at least on outlet opening).

12. **Regarding claims 39, 40, 43 and 44**, Webster discloses an infusion tube 14 is made of polyamide which acts as a thermally insulating layer, this tubing extends into the central channel (40) and extends into separate branches 41 which would then insulate at least a portion of an outlet opening (view figure 5; column 4, lines 28- column 5, line 5 and column 6, lines 27-43), this tubing can be considered to be a low thermally conducting material casing as well as being a preformed tubular member.

13. **Regarding claim 47**, Webster discloses the catheter according to claim 14, wherein the unitary electrode comprises a relatively thin metallic member coupled to the exterior of an inner portion formed of a relatively low thermally conductive material (column 4, lines 35-50).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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16. **Claims 19-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US 6,171,275) in view of Rydell (US 5,098,431).

17. **Regarding claim 19**, Webster discloses the claimed catheter, but fails to explicitly disclose wherein the first end includes: a core manufactured from a material having low thermal conductivity and/or low electrical conductivity; and a casing having a good heat conductivity and/or good electrical conductivity relative to the core. However, Rydell discloses a core manufactured from a material having low thermal conductivity and/or low electrical conductivity; and a casing having a good heat conductivity and/or good electrical conductivity relative to the core (column 3, lines 12- 20). It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Webster with the core and casing taught by Rydell. Doing so would allow the catheter to work properly with the operating electrodes within the body.

18. **Regarding claim 20**, Webster discloses the claimed catheter, wherein the core is made of plastic, ceramic, or glass (column 6, lines 3-15, and but fails to disclose wherein the casing is made of metal. However, Rydell discloses wherein the core is made of plastic, ceramic, or glass, and wherein the casing is made of metal (column 3, lines 12-20). It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Webster with the ceramic core and metal casing taught by Rydell. Doing so would allow the catheter to work properly with the operating electrodes within the body.

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19. **Regarding claim 21**, Webster discloses the catheter according to claim 19, wherein the temperature sensor comprises a thermocouple coupled to a portion of the casing (column 7; lines 5-14).

20. **Claims 15 and 29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US 6,171,275) in view of Brucker (US 6,017,338).

21. **Regarding claims 15 and 29**, Webster discloses the claimed catheter but fails to disclose wherein said at least one bore couples to a lateral exterior portion of the unitary electrode and wherein said at least one outlet opening comprises a plurality of outlet openings. However, Brucker discloses an irrigated electrode catheter that has a plurality of outlet openings as well as having a bore that extends from the end of an irrigation channel extending to the exterior portion of an electrode (view figure 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a plurality of irrigation openings in an ablation electrode catheter. Doing so would irrigate the ablation area as well as increase the ablation target area by creating a virtual electrode as well as preventing clotting from occurring at the tip.

Response to Arguments

22. Applicant's arguments with respect to claims 14-22, 27-29, 31, 38-48 have been considered but are moot in view of the new ground(s) of rejection.

23. Webster has been defined above as being unitary in the rejection of claims 14, 18 and 27.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SCOTT whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Thursday, 8:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
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